Commonwealth of Massachusetts – Department of Public Health – Bureau of Health Professions Licensure
Office of Public Protection – Board of Registration in Pharmacy
Non - Sterile Compounding Inspection Form

DATE(S) OF INSPECTION:	**ISP# -**
PHARMACY DBA NAME:	
STORE NUMBER:	
STREET ADDRESS:	
CITY / STATE / ZIP:	
TELEPHONE:	
FAX:	
EMAIL:	
PHARMACY LIC. NUMBERS:	
PHARMACY LIC. EXPIRATION:	
MANAGER OF RECORD (MOR):	
MOR LIC. NUMBER:	
COMPOUNDING RESEARCH MEDICATION(S):	☐ **YES** ☐ **NO**
COMPOUNDING DIETARY / NUTRITIONAL SUPPLEMENTS:	☐ **YES** ☐ **NO**
HIGHEST COMPOUNDING RISK LEVEL:	☐ **SIMPLE** ☐ **MODERATE** ☐ **COMPLEX**
DAILY PHARMACY VOLUME (NON-STERILE COMPOUNDING):	
HOURS OF OPERATION:	**M – F:** **SAT:** **SUN:**

A. Regulatory Requirements			
Item#	**Requirements**	**Yes/No/NA**	**Additional Information**
1	Compounder is appropriately licensed.		
2	If compounder prepares a significant number of non-patient specific preparations (e.g. >5% of the compounder's volume), the compounder is registered as a drug manufacturer with the FDA, if required.		
3	If compounder prepares non-patient specific controlled substances preparations, the compounder is registered as a drug manufacturer with the DEA.		
4	All pharmacists are licensed in the state in which they are practicing.		
5	All pharmacy technicians are licensed or registered in the state in which they are practicing.		
6	Compounder meets or exceeds state required pharmacist-to-pharmacy technician ratios for the state in which the compounding center is located.		
7	If an FDA-approved product is commercially available (not on backorder), the compounder does not prepare the same drug formulation using non-sterile powders or other components.		
8	When no commercial source exists to prepare compounded products, the compounder uses USP grade bulk ingredients obtained from a GMP compliant supplier. If yes, the compounder provides a certificate of analysis and potency testing of all bulk ingredients used.		
9	Compounded preparations are dispensed pursuant to a valid prescription/order of an authorized practitioner to a specific patient.		
10	Compounder meets regulatory requirements for handling of hazardous agents.		

B. Quality Requirements			
Item#	**Requirements**	**Yes/No/NA**	**Additional Information**
11	Compounder can provide documentation that confirms staff competency (garbing and hand hygiene, compounding technique and related practices, and cleaning and disinfection procedures) is evaluated prior to compounding of actual drug preparations.		
12	Compounder can provide documentation that confirms that pharmacists and pharmacy technicians are pre-qualified to perform their assigned duties.		
13	United States Pharmacopeia (USP), National Formulary (NF) or Food Chemicals Codex (FCC) Substance is utilized as the source ingredients for compounding all preparations		
14	Compounders shall attempt to use components manufactured in an FDA-registered facility		
15	Compounded preparations are prepared from ingredients that meet requirements of the compendial monograph for those individual ingredients for which monographs are provided.		
16	Does compounding facility compound preparations intended for use as a dietary or nutritional supplement? (either yes or N/A)		
17	Does compounding facility utilize any components obtained or derived from ruminant animals (e.g. bovine, caprine, ovine)? (either yes or N/A)		
18	Does compounding facility have available the FDA list of components that have been withdrawn or removed from the market for safety or efficacy reasons. (see www.FDA.gov)		

Item#	Requirements	Yes/No/NA	Additional Information
19	Does compounding facility compound preparations for food-producing animals? (either yes or N/A)		
20	Are components used in the compounding of preparations stored as directed by the manufacturer, or per USP, NF. FCC monograph requirements?		
21	Compounder provides customers with substantial evidence that supports beyond-use-dating (BUD) for compounded preparations as identified in USP <1191>. BUD is appropriately identified on preparation container or label.		
22	Compounder performs studies to determine extended BUDs, using evidence-based and validated stability testing procedures for which no extended BUD evidence exists.		
23	Compounder has a policy that requires validation of new or changed facilities, equipment, processes, container types, for sterility, and repeatability. (i.e., Change Control)		
24	There is a mechanism to promptly address equipment problems.		
25	A quality assurance program for compounding includes at least the following separate, but integrated components: (1) training; (2) standard operating procedures; (3) documentation; (4) verification; (5) testing; (6) cleaning and disinfecting; (7) containers, packaging, repackaging, and storage.		

Item#	Requirements	Yes/No/NA	Additional Information
	Ongoing Monitoring		
26	**Non-sterile Compounding - simple preparations** [A preparation that has a USP monograph or appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and BUD; or manipulating commercial product that may require the addition of one or more ingredients.]		
27	**Non-sterile Compounding - medium preparations** [A preparation that requires special calculations or procedures to determine quantities of components per preparation or per individualized dosage units; or making a preparation for which stability data for that specific formulation are not available.]		
28	**Non-sterile Compounding - complex preparations** [A preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes.]		
29	Compounder develops and implements methods for improving quality based on analyzed data.		
30	Compounder evaluates and continuously monitors the methods used for the packaging, handling, and transport of compounded medication?		
31	Compounder evaluates and continuously monitors the storage of compounding components to ensure compliance with appropriate storage conditions.		

Item#	Requirements	Yes/No/NA	Additional Information
32	Drug storage refrigerators, freezers and medication storage areas have twice daily monitoring and documentation of temperatures.		
33	Personnel inspect all drug storage areas routinely to ensure drugs are stored separately from food.		
34	Solutions, medications, equipment, and supplies (in all areas) are stored per the manufacturer or USP requirements and are inspected routinely (per P&P) for proper conditions of light, temperature, moisture, and ventilation.		
35	Personnel determine whether a compounded medication not administered as originally intended can be used for an alternate patient or under alternate conditions		
36	Didactic training, visual process validation and written assessment of personnel is documented.		
37	Are personnel who compound hazardous drugs fully trained in the storage, handling, and disposal of these drugs?		
38	Do personnel receive training prior to preparing and handling hazardous drugs and verified by testing specific hazardous drug preparation techniques? Is training repeated annually?		
39	Does the annual training and assessment for hazardous drugs include didactic overview including mutagenic, teratogenic, and carcinogenic properties?		
40	Is there a process for ongoing training for each new hazardous drug that enters the marketplace?		

Item#	Requirements	Yes/No/NA	Additional Information
41	Do compounding personnel of reproductive capability confirm in writing that they understand the risks of handling hazardous drugs as part of the orientation process and repeat acknowledgment annually?		
42	Does the compounder maintain results of quality control procedures (e.g. weight range of filled capsules, pH of aqueous liquids, etc)?		
43	Does the compounding record contain documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver?		
44	Does the compounder observe the finished preparation to ensure that it appears as expected to ensure accuracy and completeness?		
45	The compounding facility investigates all discrepancies and takes appropriate corrective action prior to dispensing to patients?		
46	Documentation is available for any quality control issues and any adverse reactions reported by the patient or caregiver?		

C. Compounding Environment			
Item#	**Requirements**	**Yes/No/NA**	**Additional Information**
47	Space is sufficient for the type and amount of compounding done.		
48	The space provides for orderly placement of equipment and materials to prevent mix-ups between ingredients, containers, labels, in-process materials, finished preparations.		
49	Procedures are implemented to prevent cross-contamination.		
50	Areas used for **sterile** preparation are separate and distinct from areas used for **non-sterile** preparation.		
51	The compounding area is well-lighted.		
52	Heating, ventilation and air conditioning systems are controlled. A constant temperature is maintained 24 hours per day, 7 days per week.		
53	The bulk storage area is adequately arranged, proper temperature and humidity maintained and suitably controlled.		
54	The compounding areas are maintained in a clean and sanitary condition.		
55	Hot and cold potable water is supplied for hand and equipment washing in the compounding area. Soap or detergent and single-use towels or driers are readily available.		
56	Is the plumbing system free of defects that could contribute to contamination of any compounded product?		

Item#	Requirements	Yes/No/NA	Additional Information
57	Does the heating, ventilation, and air conditioning system control the compounding environment to avoid the decomposition or result in the contamination of compounding materials or compounded products?		
58	Does the compounding environment meet the manufactures requirements for the storage and preparation of drug products?		
59	If no specific directions or limitations are provided in the individual USP drug or product monograph or labeling (that is recognized by USP) does the environmental conditions for storage and distribution, regardless of quantity, include protections from moisture, freezing, excessive heat, and from light, where necessary?		
60	Are components, equipment, and all containers stored off the floor?		
61	Does the pharmacy provide space sufficient to prevent contamination and permit inspection and cleaning of the compounding and storage areas?		
62	Does the pharmacy ensure that hazardous compounds and drugs are stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other persons?		
63	Does the disposal of hazardous drugs and waste comply with all applicable federal and state regulations?		

Item#	Requirements	Yes/No/NA	Additional Information
64	Are the compounding equipment, utensils, and containers used for packaging composed of suitable materials that are neither reactive, additive, nor sorptive and will not affect or alter the purity of the compounded preparations?		
65	Does the storage of compounding equipment, utensils and packaging containers protect them from contamination and are they located in a manner to facilitate the use, maintenance, and cleaning?		
66	Are automated, mechanical, electronic, and other types of equipment checked/inspected immediately prior to use and routinely as part of a preventative maintenance program to ensure suitability for use and proper performance?		
67	Is all equipment appropriately cleaned after use? (evidence of soiled equipment and tools indicates inappropriate cleaning)		
68	Are there processes that ensure extra care for cleaning of equipment and tools used for hazardous compounding?		
69	Is all equipment for hazardous compounding dedicated for such use?		
70	Does the compounding facility utilize disposable equipment when compounding hazardous drugs to reduce the chances of bioburden and cross-contamination? (Yes or N/A)		
71	The compounding record is signed and dated affirming that all procedures were carried out properly to ensure uniformity, identity, strength, quantity and purity.		

Item#	Requirements	Yes/No/NA	Additional Information
72	All substances have a complete label, batch control number and future BUD on the container.		
73	When manufactured products are used for compounding, the labels contain a batch control number and a future BUD.		
74	Capsules, powders, lozenges and tablets are prepared per the standard practices and precautions for these dosage forms.		
75	Emulsions, solutions and suspensions are prepared per the standard practices and precautions for these dosage forms.		
76	Suppositories are prepared per the standard practices and precautions for these dosage forms.		
77	Creams, topical gels, ointments and pastes are prepared per the standard practices and precautions for these dosage forms.		
78	The equipment generally is of appropriate design and size for the compounding that is performed.		
79	All equipment is thoroughly cleaned immediately after use to avoid cross-contamination.		
80	Equipment used for allergenic ingredients is appropriately handled, cleaned and stored immediately after use.		
81	All work surfaces are cleaned of loose materials and residue from spills before compounding.		
82	Product labels are appropriate and complete for safe storage use		
83	Trash is disposed of in a safe, sanitary and timely manner (at least daily).		

D. Compounding Procedures			
Item#	**Requirements**	**Yes/No/NA**	**Additional Information**
84	There is no smoking, food, drink, or chewing gum allowed in the compounding area at any time.		
85	At all steps in the compounding, dispensing, and storage process, the compounder shall observe the compounded drug preparation for signs of instability.		
86	Primary Engineering Controls (PEC): e.g., airflow workbench (powder hood) and negative pressure safety storage cabinets (Hazardous Drug Storage) provide negative airflow with a minimum of 12 air exchanges under dynamic conditions.		
87	Do packaging and storage containers used in the packaging of compounded preparations meet USP requirements (USP<660>; USP<661>; USP<671>; USP<681>; USP<1136>; USP<1146>)?		
88	All significant procedures performed in the compounding area have standard operating procedures (SOP's).		
89	All policies and procedures or SOP's are developed for the facilities, equipment, personnel, preparation, packaging, and storage of compounded preparation to ensure accountability, accuracy, quality, safety, and uniformity in compounding.		
90	Before putting on gloves, the nails should be cleaned, and the hands, and wrists, should be washed thoroughly for at least 30 seconds with warm water and antimicrobial skin cleanser.		
91	All components utilized in compounding are rotated so that the oldest stock is utilized first?		

Item#	Requirements	Yes/No/NA	Additional Information
92	All components are properly labeled and stored appropriately including opened and partially used containers?		
93	Compounding personnel check the quality, purity, amount, and identity of all ingredients		
94	Correct compounding procedures are used		
95	During compounding, periodically disinfect gloves with 70% isopropyl alcohol and allow them to dry thoroughly before continuing.		
96	Product labels are appropriate and complete for safe use		
97	Deficiencies in compounding procedures can be rapidly identified and corrected.		
98	Completed compounded products are maintained in a separate area away from the active compounding area.		
99	Prescription containers are labeled to contain: name of preparation; internal identification number; beyond-use date; initials of compounder who prepared the label; storage requirements; other statements as required by law.		
100	The compounding log is annotated and formulation documented.		
101	**Non-aqueous Formulations -** The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.		
102	**For Water-Containing Oral Formulations -** The BUD is not later than 14 days when stored at controlled cold temperatures.		
103	**For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations -** The BUD is not later than 30 days.		

E. Records Management			
Item#	**Requirements**	**Yes/No/NA**	**Additional Information**
104	The record keeping requirements of the state are followed.		
105	The pharmacy is licensed to handle controlled substances.		
106	Compounding records and documents are maintained for the time required by the state.		
107	Does compounder provide written standard operating procedures (SOP's) for pharmaceutical compounding for the facility to include equipment use, personnel, preparation, packaging, and the storage of compounded preparations to ensure accountability, accuracy, quality, safety, and uniformity in compounding?		
108	Do written standard operating procedures (SOP's) establish procedural consistency and provide a reference for orientation and training of personnel?		
109	Material Safety Data Sheets or Safety Data Sheets (MSDS or SDS) are readily accessible to all employees working with drug substances or bulk chemicals located within the facility. Employees know how to access MSDS file.		
110	A procedure is defined for recalls. The recall file should be maintained with information concerning any applicable recalled products affecting the pharmacy.		
111	Compounder provides minimum guaranteed shelf life upon delivery.		

Item#	Requirements	Yes/No/NA	Additional Information
112	A detailed formulation record is maintained for each non-sterile compounded preparation and includes: name of preparation, strength and dosage form; all ingredients and their quantities; equipment used for the preparation; mixing instructions to include order of mixing, temperatures, duration of mixing and other pertinent factors; BUD; container used; storage requirements; quality control procedures.		
113	A detailed compounding record is maintained for each compounded non-sterile preparation and includes: • Name, strength and dosage of the preparation; • Formulation record reference; • Names and quantities of all components; • Manufacturer or supplier and lot numbers of components; • Total number of dosage units compounded; • Name of person compounding the preparation; • Date of compounding; • Assigned internal identification number of the prescription number; • Assigned beyond-use date; • Results of quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids, etc.); • Name of person completing the quality control procedures; • Name of person who approved the preparations; • Duplicate label as described in the master formulation record; • Description of the final preparation.		

Item#	Requirements	Yes/No/NA	Additional Information
114	Compounder provides quality control history and quality assurance trend reports on a regular basis and upon request.		
115	Compounder provides pedigree information that documents that they do not purchase products outside of traditional drug distribution networks or through secondary wholesalers.		
116	Compounder has documented processes and procedures (including shipping validation studies) to ensure that preparations leaving the site retain their integrity and stability through the shipping cycle.		
117	Documentation is available that cleaning methods and agents are effective in preventing contamination and cross-contamination of non-sterile materials and drugs within the compounding preparations areas.		

Comments:

Comments:

Plan of Correction Issued: ☐ Yes ☐ No

If yes, I will provide a plan of correction for all findings within 15 business days.

Inspector: _____ **Date:** _____

Inspector: _____ **Date:** _____

Inspector: _____ **Date:** _____

Plan of Correction instructions: https://www.mass.gov/doc/plan-of-correction-directions-for-licensees-0/download

Print

Plan of Correction template: https://www.mass.gov/doc/plan-of-correction-template-0/download